

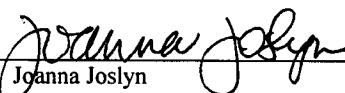


**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re United States Patent Application of:	)	Docket No.:	4115-194	
Applicants:	PAUZA, C. David, et al.	)	Conf. No.:	7524
Application No.:	10/539,677	)	Art Unit:	Not Yet Assigned
Date Filed:	June 16, 2005	)	Examiner:	Not Yet Assigned
Title:	VACCINES AGAINST HIV-1 TAT PROTEIN TO GENERATE NEUTRALIZING ANTIBODIES	)	Customer No.:	23448

**FIRST CLASS MAIL CERTIFICATE**

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313, First Class Mailed under the provisions of 37 CFR 1.8.

  
\_\_\_\_\_  
Joanna Joslyn

\_\_\_\_\_  
January 31, 2006  
\_\_\_\_\_  
Date of Mailing

**INFORMATION DISCLOSURE STATEMENT IN  
U.S. PATENT APPLICATION NO. 10/539,677**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO/SB/08A. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

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This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.

Respectfully submitted,



\_\_\_\_\_  
Steven J. Hultquist  
Reg. No. 28,021  
Attorney for Applicants

**INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW**  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4115-194

**Enclosures:**  
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FEB 02 2006

PTO/SB/08b (07-05)

Approved for use through 06/30/2006. OMB 0651-0031  
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Sheet	1	of	6	Attorney Docket Number	4115-194
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AA	ALBINI, A., ET AL., Identification of a novel domain of HIV Tat involved in monocyte chemotaxis, J. of Biological Chem., June 1998, Page(s) 15895-15900, Volume 273, Number 26	
	AB	ALBINI, A., ET AL., HIV-1 Tat protein mimicry of chemokines, Proc. Natl. Acad. Sci., October 1998, Page(s) 13153-13158, Volume 95	
	AC	ALLEN, T.M., ET AL., Tat-vaccinated macaques do not control simian immunodeficiency virus SIVmac239 replication, Journal of Virology, April 2002, Page(s) 4108-4112, Volume 76, Number 8	
	AD	BADOU, A., ET AL., Tat protein of human immunodeficiency virus type 1 induces interleukin-10 in human peripheral blood monocytes..., Journal of Virology, November 2000, Page(s) 10551-10562, Volume 74, Number 22	
	AE	BARILLARI, G.R., ET AL., The Tat protein of human immunodeficiency virus type I, a growth factor for AIDS Kaposi sarcoma..., Proc. Natl. Acad. Sci., 1993, Page(s) 7941-7945, Volume 90	
	AF	BARTZ, S.R. AND EMERMAN, M., Human Immunodeficiency virus type 1 Tat induces apoptosis and increases sensitivity to apoptotic signals..., Journal of Virology, March 1999, Page(s) 1956-1963, Volume 73, Number 3	
	AG	BAYER, P., ET AL., Structural studies of HIV-1 Tat protein, Journal Mol. Biol., 1995, Page(s) 529-535, Volume 247	
	AH	BENJOUAD, A., ET AL., Cytotoxic effect on lymphocytes of Tat from human immunodeficiency virus (HIV-1), Fed. European Biochem. Societies Letters, March 1993, Page(s) 119-124, Volume 319, Number 1,2	
	AI	BOYKINS, R.A., ET AL., Cutting edge: a short polypeptide domain of HIV-1 Tat protein mediates pathogenesis, J. of Immunology, 1999, Page(s) 15-20, Volume 163	
	AJ	BRAKE, D.A., ET AL., Identification of an Arg-Gly-Asp (RGD) cell adhesion site in human immunodeficiency virus type 1 transactivation protein, tat, J. of Cell Biology, September 1990, Page(s) 1275-1281, Volume 111	

Examiner Signature	/Louise Humphrey/	Date Considered	05/15/2008
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				<i>First Named Inventor</i>	Pauza et al.
				<i>Art Unit</i>	Unassigned
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	AK	BRAKE, D.A., ET AL., Characterization of murine monoclonal antibodies to the tat protein from human immunodeficiency virus type 1, Journal of Virology, February 1990, Page(s) 962-965, Volume 64, Number 2		
	AL	CARAFOL, A., ET AL., Control of SHIV-89.6P-infection of cynomolgus monkeys by HIV-1 Tat protein vaccine, Nature Medicine, June 1999, Page(s) 643-650, Volume 5, Number 6		
	AM	COHEN, S.S., ET AL., Pronounced acute immunosuppression in vivo mediated by HIV Tat challenge, Proc. Natl. Acad. Sci., September 1999, Page(s) 10842-10847, Volume 96		
	AN	CORDINGLEY, M.G., ET AL., Sequence-specific interaction of Tat protein and Tat peptides with the transactivation-responsive sequence element..., Proc. Natl. Acad. Sci., November 1990, Page(s) 8985-8989, Volume 87		
	AO	DELLING, U., ET AL., The number of positively charged amino acids in the basic domain of Tat is critical for transactivation..., Proc. Natl. Acad. Sci., July 1991, Page(s) 6234-6238, Volume 88		
	AP	DE PAULIS, A., ET AL., Tat protein is an HIV-1 encoded β-chemokine homolog that promotes migration and up-regulates CCR3 expression..., J. of Immunology, 2000, Page(s) 7171-7179, Volume 165		
	AQ	ENSOLI, B., ET AL., Release, uptake, and effects of extracellular human immunodeficiency virus type 1 Tat protein on cell growth ..., Journal of Virology, January 1993, Page(s) 277-287, Volume 67, Number 1		
	AR	FAWELL, S., ET AL., Tat-mediated delivery of heterologous proteins into cells, Proc. Natl. Acad. Sci., January 1994, Page(s) 664-668, Volume 91		
	AS	GALFRE, G. AND MILSTEIN, C., Preparation of monoclonal antibodies: strategies and procedures, Methods Enzymol., 1981, Page(s) 3-46, Volume 73		
	AT	GALLO, R.C., Tat as one key to HIV-induced immune pathogenesis and Tat toxoid as an important component of a vaccine, Proc. Natl. Acad. Sci., July 1999, Page(s) 8324-8326, Volume 96		

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<i>First Named Inventor</i>	Pauza et al.
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<i>Examiner Name</i>	Unassigned

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	AU	GOLDSTEIN, G., ET AL., Two B cell epitopes of HIV-1 Tat protein have limited antigenic polymorphism in geographically diverse HIV-1 strains, Vaccine, 2001, Page(s) 1738-1746, Volume 19	
	AV	GOLDSTEIN, GIDEON, HIV-1 Tat protein as a potential AIDS vaccine, Nature Medicine, September 1996, Page(s) 960-964, Volume 1, Number 9	
	AW	GOLDSTEIN, G.G., ET AL., Minimization of chronic plasma viremia in rhesus macaques immunized with synthetic HIV-1 Tat peptides..., Vaccine, 2000, Page(s) 2789-2795, Volume 18	
	AX	GREGOIRE, C., ET AL., Homonuclear H-NMR assignment and structural characterization of human immunodeficiency virus type 1 Tat mal protein, Biopolymers, 2001, Page(s) 324-335, Volume 62	
	AY	GRINGERI, A., ET AL., Safety and immunogenicity of HIV-1 Tat toxoid in immunocompromised HIV-1 infected patients, Journal of Human Virology, May/June 1998, Page(s) 293-298, Volume 1, Number 4	
	AZ	GUTHEIL, W.G., ET AL., Human immunodeficiency virus 1 Tat binds to dipeptidyl aminopeptidase IV (CD26)..., Proc. Natl. Acad. Sci., July 1994, Page(s) 6594-6598, Volume 91	
	BA	HALL, T.A., BioEdit: a user-friendly biological sequence alignment editor and analysis program for Windows 95/98/NT, Nucleic Acids Symposium Series, 1999, Page(s) 95-98, Volume 41	
	BB	HUANG, L., ET AL., Tat protein induces human immunodeficiency virus type 1 (HIV-1) coreceptors and promotes infection with both macrophage-tropic..., Journal of Virology, November 1998, Page(s) 8952-8960, Volume 72, Number 11	
	BC	ITO, M., ET AL., HIV type 1 Tat protein inhibits interleukin 12 production by human peripheral blood mononuclear cells, AIDS Research and Human Retroviruses, 1998, Page(s) 845-849, Volume 14, Number 10	
	BD	JEANG, K.T., ET AL., Multifaceted activities of the HIV-1 transactivator or transcription, Tat, J. Biol. Chem., October 1999, Page(s) 28837-28840, Volume 274, Number 41	

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	BE	KATSIKIS, P.D., ET AL., HIV type 1 Tat protein enhances activation- but not Fas (CD95)-induced peripheral blood T cell apoptosis..., International Immunology, 1997, Page(s) 835-841, Volume 9, Number 6	
	BF	LAMBERT, J., Tat toxoid: its potential role as an HIV vaccine, J. of Human Virology, 1998, Page(s) 249-250, Volume 1	
	BG	LE BUANEC, H., AND B. BIZZINI, Procedures for preparing biologically inactive, but immunogenic HIV-1 Tat protein (Tat Toxoid) for human use, Biomed. Pharmacother., 2000, Page(s) 41-44, Volume 54	
	BH	MACHO, A.M., ET AL., Susceptibility of HIV-1-TAT transfected cells to undergo apoptosis, Oncogene, 1999, Page(s) 7543-7551, Volume 18	
	BI	MANN, D.A. AND FRANKEL, A.D., Endocytosis and targeting of exogenous HIV-1 Tat protein, EMBO Journal, 1991, Page(s) 1733-1739, Volume 10, Number 7	
	BJ	PAUZA, C.D., ET AL., Vaccination with Tat toxoid attenuates disease in simian/HIV-challenged macaques, Proc. Natl. Acad. Sci., 2000, Page(s) 3515-3519, Volume 97, Number 7	
	BK	PHILIPPON, V., ET AL., The basic domain of the lentiviral Tat protein is responsible for damages in mouse brain: involvement of cytokines, Virology, 1994, Page(s) 519-529, Volume 205	
	BL	RE, M.C., ET AL., Effect of antibody to HIV-1 Tat protein on viral replication in vitro and progression of HIV-1 disease in vivo, Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology, 1995, Page(s) 408-416, Volume 10	
	BM	RE, M.C., ET AL., Antibodies against full-length Tat protein and some low-molecular-weight Tat-peptides correlate with low or undetectable., Journal of Clinical Virology, 2001, Page(s) 81-89, Volume 21	
	BN	RODMAN, T.C., ET AL., Epitopes for natural antibodies of human immunodeficiency virus (HIV)-negative (normal) and HIV-positive sera..., Proc. Natl. Acad. Sci., August 1993, Page(s) 7719-7723, Volume 90	

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	BO	RODMAN, T.C., ET AL., Circulating natural IgM antibodies and their corresponding human cord blood cell-derived Mabs specifically combat..., Experimental Hematology, , Page(s) 1004-1009, Volume 29	
	BP	RUBEN, S., ET AL., Structural and functional characterization of human immunodeficiency virus tat protein, Journal of Virology, 1989, Page(s) 1-8, Volume 63, Number 1	
	BQ	RUSNATI, M., ET AL., The basic domain in HIV-1 Tat protein as a target for polysulfonated heparin-mimicking extracellular Tat antagonists, J. Biol. Chem., 1998, Page(s) 16027-16037, Volume 273, Number 26	
	BR	SADAIE, M.R., ET AL., Site-directed mutagenesis of two trans-regulatory genes (tat-III, trs) of HIV-1, Science, February 1988, Page(s) 910-913, Volume 239, Number 4842	
	BS	SCHWARZE, S.R., ET AL., In vivo protein transduction: delivery of a biologically active protein into the mouse, Science, 1999, Page(s) 1569-1572, Volume 285, Number 5433	
	BT	SECCHIERO, P., ET AL., Extracellular HIV-1 Tat protein up-regulates the expression of surface CXC-chemokine receptor 4 in resting CD4 <sup>+</sup> T cells, J. Immunol., 1999, Page(s) 2427-2431, Volume 162	
	BU	SECCHIERO, P., ET AL., Pivotal role of cyclic nucleoside phosphodiesterase 4 in Tat-mediated CD4 <sup>+</sup> T cell hyperactivation and HIV type 1..., Proc. Natl. Acad. Sci., December 2000, Page(s) 14620-14625, Volume 97, Number 26	
	BV	SILVERA, P., ET AL., Outcome of simian-human immunodeficiency virus strain 89.6p challenge following vaccination of rhesus macaques..., Journal of Virology, April 2002, Page(s) 3800-3809, Volume 76, Number 8	
	BW	SUBRAMANYAM, M., ET AL., Mechanism of HIV-1 Tat induced inhibition of antigen-specific T cell responsiveness, J. of Immunol., March 1993, Page(s) 2544-2553, Volume 150, Number 6	
	BX	TYAGI, M., ET AL., Internalization of HIV-1 Tat requires cell surface heparan sulfate proteoglycans, J. Biol. Chem., February 2001, Page(s) 3254-3261, Volume 276, Number 5	

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	BY	VAN BAALEN, C.A., ET AL., Human immunodeficiency virus type 1 Rev- and Tat-specific cytotoxic T lymphocyte frequencies inversely correlate with..., J. Gen. Virol., 1997, Page(s) 1913-1918, Volume 78	
	BZ	VISCIDI, R.P., ET AL., Inhibition of antigen-induced lymphocyte proliferation by Tat protein from HIV-1, Science, December 1989, Page(s) 1606-1608, Volume 246, Number 4937	
	CA	VIVES, E., ET AL., A truncated HIV-1 Tat protein basic domain rapidly translocates through the plasma membrane and .., J. Biol. Chem., March 1997, Page(s) 16010-16017, Volume 272, Number 25	
	CB	WEEKS, K.M., ET AL., RNA recognition by Tat-derived peptides: interaction in the major groove? Cell - ABSTRACT ONLY, August 1991, Page(s) 577-588, Volume 66	
	CC	WEISS, J.M., ET AL., HIV-1 Tat induces monocyte chemoattractant protein-1-mediated monocyte transmigration across a model of the human..., J. of Immunol., 1999, Page(s) 2953-2959, Volume 163	
	CD	WESTENDORP, M.O., ET AL., Sensitization of T cells to CD95-mediated apoptosis by HIV-1 Tat and gp120, Nature, June 1995, Page(s) 497-500, Volume 375	
	CE	WRENGER, S., ET AL., The N-terminal structure of HIV-1 Tat is required for suppression of CD26-dependent T cell growth, J. Biol. Chem., 1997, Page(s) 30283-30288, Volume 272, Number 48	
	CF	ZAGURY, D., ET AL., Interferon alpha and Tat involvement in the immunosuppression of uninfected T cells and C-C chemokine decline in AIDS, Proc. Natl. Acad. Sci., March 1998, Page(s) 3851-3856, Volume 95	
	CG	ZAGURY, J.F., ET AL., Antibodies to the HIV-1 Tat protein correlated with nonprogression to AIDS;..., J. of Human Virology, 1998, Page(s) 282-292, Volume 1, Number 4	
	CH	ZHANG, M., ET AL., Identification of potential HIV-induced source of bystander-mediated apoptosis in T cells: upregulation of TRAIL..., J. Biomed. Sci., 2001, Page(s) 290-296, Volume 8	

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